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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087913,056	10/22/97	YAMAMOTO	N KP-8240

ROBERT J PATCH  
YOUNG & THOMPSON  
745 S 23RD ST  
SUITE 200  
ARLINGTON VA 22202

HM42/0111

EXAMINER
WEBMAN, E

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/11/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
08/913056Applicant(s)  
YAMAMOTOExaminer  
WEBMANGroup Art Unit  
1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 10/9/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1-27 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-27 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazis et al. in view of Roberts et al., Azria et al., Kissel et al., Japan 3-5427, EPA-215697, and Cooper.

Mazis et al. teach transdermal delivery comprising a permeation enhancer, a vasodilator, and an active (abstract). The active is any transdermally deliverable drug, including proteinaceous drugs such as insulin (column 3, lines 30-33, column 4, line 15).

Roberts teach particular vasodilators such as nitroglycerin, prostaglandins and calcium antagonists (column 8, lines 5-9).

Azria et al. teach taurocholic acid as an absorption enhancer for calcitonin. (Abstract).

Kissell et al. teach salts of fusidic acid as enhancers for octreotide (Title).

Japan 3-5427 teaches glycyrrhizic acid as an absorption enhancer for calcitonin.

EPA 215697 teach acyl carnitines as enhancers (abstract). Polypeptides are disclosed (page 3 line 13-page 6 line 2).

Cooper teaches acyl Azacyclo heptane-ones as enhancers (abstract). The enzyme asparaginase is disclosed as an active. (Column 20 line 18).

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It would have been obvious to use the claimed ~~unsodilators~~<sup>V4</sup> in the Mazis et al.

composition in view of Roberts et al. and to use the particular claimed absorption enhancers in view of Azria et al., Kissler et al., Japan 3-5427 et al., EPA-21697, EPA 94157, and Cooper.

Applicants argue that Masiz et al. only teaches delivery through the skin, however delivery through mucosal tissue is indicated by disclosure of activation via saliva (claim 16).

Applicants also argue that ~~M~~<sup>a</sup>zis et al. require an irritant, however such an agent is optional (Abstract).

The declaration of Mr. Yamamoto has been considered but is not deemed to overcome the rejection because whatever synergy was observed is inherent in Mazis et al. At best, whatever synergy is demonstrated is limited to the particular combination of active, vasodilator and absorption promotor demonstrated.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

E. Webman:jmr

Dec. 29, 1998



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500